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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,671	12/20/2005	Anders Vikso Nielsen	10473.204-US	3643

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NOVOZYMES NORTH AMERICA, INC.  
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NEW YORK, NY 10110

EXAMINER
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MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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08/06/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,671	<b>Applicant(s)</b> NIELSEN ET AL.	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-65 is/are pending in the application.
- 4a) Of the above claim(s) 61-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)            |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input checked="" type="checkbox"/> Other: <u>Alignment 1</u> . |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/22/2005,12/4/2006,8/16/2007,11/29/2007.

### **DETAILED ACTION**

A response and amendment were received and entered on March 12, 2009. Claims 1-46 are cancelled. New claims 47-65 have been added. Claims 47-65 are pending.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, as set forth in the restriction requirement mailed on February 12, 2009, in the reply filed on March 12, 2009 is acknowledged. The traversal is on the ground(s) that there is unity between the groups. This is not found persuasive because there is no special technical feature that is common to the groups. Specifically, the process recited in claim 47 lacks an inventive step, as discussed in detail in the rejections below. Briefly, the process of claim 47 is rendered obvious by Shi et al. (US 6,054,302) in view of Walon (US 4,235,965). The requirement is still deemed proper and is therefore made FINAL.
2. Claims 61-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.
3. Claims 47-60 are examined on the merits in this office action.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The claim is rendered indefinite by the recitation, "the enzyme does not comprise a catalytic module." The metes and bounds of the claim are unclear because applicant could intend to recite that the enzyme does not comprise an active site, that the enzyme does not comprise activity at the active site, or that there is nothing present on the enzyme that could result in catalysis (i.e. the enzyme could not be acted on by another enzyme). Furthermore, the term "catalytic module" is not defined in the specification. Thus, the properties of the enzyme recited in the claim would be unclear to one of ordinary skill in the art.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
10. Claims 47-56 and 60 are rejected under 35 U.S.C. 103(a) as obvious over Shi et al. (US 6,054,302) in view of Walon (US 4,235,965), as evidenced by the attached sequence alignment (Alignment 1). Claim 47 recites a process for producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature of said granular starch to the action of a first enzyme and a second enzyme, wherein (a) the first enzyme (i) is a member of the glycoside hydrolase family 13; (ii) has alpha-1,4-glucosidic hydrolysis activity, and; (iii) comprises a functional carbohydrate-binding module (CBM) belonging to CBM family 20, wherein the CBM comprises an amino acid sequence having at least 90% homology to SEQ ID NO:2. Claim 48 recites that the CBM of claim 47 comprises an amino acid sequence having at least 95% homology to the amino acid sequence of SEQ ID NO:2. Claim 49 recites that the starch slurry has 20-55% dry solids granular starch. Claim 50 recites that at least 85% of the dry solids of the granular starch are

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converted into a soluble starch hydrolysate. Claim 51 recites that the granular starch is further subjected to the action of isoamylase and pullulanase. Claim 52 recites that the temperature is at least 58 degrees C. Claim 53 recites that the pH is 3.0 to 7.0. Claim 54 recites that the soluble starch hydrolysate has a DX of at least 94.5%. Claims 55 and 56 recite that the granular starch is derived from a variety of sources. Claim 60 recites that the first enzyme does not comprise a catalytic module.

11. Shi discloses a method of producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature to the action of two or more enzymes (abstract, col. 4, lines 15-31, col. 9, lines 46-49). The enzymes used in the method of Shi are alpha amylase, beta amylase or glucoamylase, such as a fungal or bacterial enzymes (col. 6, lines 15-29, col. 9, lines 46-49). The reference teaches that 30-50% dry solids may be used in the slurry (col. 3, lines 16-21), that conversion rates of 85% could be achieved (col. 1, line 62-col. 2, line 2), and that the slurry could also be subjected to isoamylase or pullulanase (col. 6, lines 15-29). The process of Shi uses temperatures greater than 58 degrees C and a pH from 3.0 to 7.0 (col. 10, lines 20-36), and uses the claimed starch sources (col. 5, lines 35-45). The reference does not specifically disclose the use of an enzyme comprising the CBM and nucleotide sequence recited in the claims.

12. Walon teaches a method for producing a soluble starch hydrolysate by subjecting a granular starch slurry at a temperature below its initial gelatinization temperature to a bacterial alpha amylase (abstract). The reference teaches that any suitable bacterial

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amylase may be used in the method, particularly those from *Bacillus* spp. (col. 2, lines 52-68).

13. At the time of the invention, methods for producing soluble starch hydrolysates comprising nearly all of the claimed elements were known, as taught by Shi and Walon. It was further known that multiple enzymes could be used in such methods, as taught by Shi, and that alpha amylases from *Bacillus* spp. were suitable in such methods, as taught by Walon. One of ordinary skill in the art would have been motivated to use an enzyme comprising the CBM recited in the claims because an enzyme comprising the CBM recited in the claims is an alpha amylase from a *Bacillus* spp. (see attached Alignment 1). Since Walon teaches that any bacterial alpha-amylase could have been used in the method, particularly one from *Bacillus* spp., and an alpha amylase comprising the claimed sequence from a *Bacillus* spp. existed at the time of the invention, one of ordinary skill in the art would have recognized that an enzyme meeting the limitations recited in the claims could have been selected at the time of the invention from the finite number of possibilities for use in the claimed method. Furthermore, one of ordinary skill in the art practicing the invention of the prior art could arrive at the claimed results, such as DX values recited in the claims, in the course of routine experimentation, since DE values of 100% were known in the art, as taught by Shi (col. 4, lines 56-65). One of ordinary skill in the art would have had a reasonable expectation of success in using the enzyme of the claims because it was known in the art that alpha amylases from *Bacillus* spp. could have been used in methods for starch hydrolysis at



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the time of the invention. It would therefore have been obvious at the time of the invention to combine the teachings discussed above to arrive at the claimed invention.

14. Claims 47-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al. (US 6,054,302) in view of Walon (US 4,235,965), as evidenced by the attached sequence alignment (Alignment 1), as applied to claims 47-56 and 60 above, and further in view of Leach (3,922,196). Claims 47-56 and 60 are discussed above. Claims 57-59 recite that the process of claim 47 is conducted in an system with ultrafiltration or microfiltration membranes and where the retentate is held under recirculation in the presence of enzymes, raw starch and water, and where the permeate is the soluble starch hydrolysate.

15. Shi discloses a method of producing a soluble starch hydrolysate, comprising subjecting an aqueous granular starch slurry at a temperature below the initial gelatinization temperature to the action of two or more enzymes (abstract, col. 4, lines 15-31, col. 9, lines 46-49). The enzymes used in the method of Shi are alpha amylase, beta amylase or glucoamylase, such as a fungal or bacterial enzymes (col. 6, lines 15-29, col. 9, lines 46-49). The reference teaches that 30-50% dry solids may be used in the slurry (col. 3, lines 16-21), that conversion rates of 85% could be achieved (col. 1, line 62-col. 2, line 2), and that the slurry could also be subjected to isoamylase or pullulanase (col. 6, lines 15-29). The process of Shi uses temperatures greater than 58 degrees C and a pH from 3.0 to 7.0 (col. 10, lines 20-36), and uses the claimed starch

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sources (col. 5, lines 35-45). The reference does not specifically disclose the use of an enzyme comprising the CBM and nucleotide sequence recited in the claims.

16. Walon teaches a method for producing a soluble starch hydrolysate by subjecting a granular starch slurry at a temperature below its initial gelatinization temperature to a bacterial alpha amylase (abstract). The reference teaches that any suitable bacterial amylase may be used in the method, particularly those from *Bacillus* spp. (col. 2, lines 52-68).

17. At the time of the invention, it would have been obvious to combine the teachings discussed above to arrive at the claimed invention, as discussed in detail in the above rejections. None of the references, however, teach that the reaction is conducted in the presence of the membranes recited in the claims.

18. Leach teaches a method for the enzymatic hydrolysis of granular starch wherein the process may occur in the presence of a membrane, such as an ultrafiltration membrane, wherein the retentate is held in the presence of membranes and the permeate is the soluble starch hydrolysate (abstract; col. 8, lines 32-39).

19. Nearly all of the elements of the claimed process were known in the art at the time of the invention, as taught by Shi and Walon. It was further known that methods for the production of soluble starch hydrolysates could be conducted in the presence of filtration systems, as taught by Leach. One of ordinary skill in the art would have been motivated to combine these teachings to arrive at the claimed invention because Leach teaches that the method is advantageous because it allows separation of the unreacted components from the reacted product. One of ordinary skill in the art would have had a

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reasonable expectation of success, and the selection of a filtration membrane for the use in such a method would have been considered a routine matter of experimentation, because the use of filtration methods with starch processes was well known in the art at the time of the invention, as taught by Leach. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

20. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

SRM